Paper No. 32

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte ROBERT FRITZ

Appeal No. 2002-0534
Application No. 08/551,326

ON BRIEF

Before WINTERS, MILLS, and GRIMES, Administrative Patent Judges.

GRIMES, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 15 and 24-37, all of the claims remaining. Claims 15 and 25-27 are representative and read as follows:

15. A muscle preserving dietary supplement comprising at least 100 mg of soy derived phosphatidylserine in combination with a physiologically beneficial amount of a protein supplement.

24. A method for optimizing muscle development during intense physical exercise which comprises ingesting an anti-catabolic nutrient, soy-derived phosphatidylserine, in an amount that suppresses elevation in the level of cortisol release resulting during the physical exercise.

25. The method of claim 25 wherein the amount of said phosphatidylserine is less than 400 mg.

26. The method of claim 26 wherein the effectiveness of said phosphatidylserine is enhanced by the step of ingesting a physiologically beneficial amount of protein.

The examiner relies on the following references:

Hager, Jörg et al. (Hager) 4,874,553 Oct. 17, 1989

Alekseyeva et al. (Alekseyeva), "Comparative Characteristics of the Lipis Composition of Lipocerebrin," Farmatsiya (Mosc), Vol. 28, No. 4, pp. 51-53 (1979)

Monteleone et al. (Monteleone), "Effects of Phosphatidylserine on the Neuroendocrine Response to Physical Stress in Humans," Neuroendocrinology, Vol. 52, pp. 243-248 (1990)

Fahey et al. (Fahey), Anabolic Steroids and Winning Without Them, Chp. 1, pp. 8-22, 27, 57-60, 75-83, and 124-131 (1991)

Solgar Gold Label (Solgar), Solgar Product Alert., Vol. 26, No. 1, (1995)

Corti-PS 20F, (Corti-PS), Product Information Sheet, manufactured by Lucas Meyer, Inc. (1995)

Claims 15 and 24-37 stand rejected under 35 U.S.C. § 103 as obvious in view of Fahey, Monteleone, Alekseyeva, Hager, Solgar, and Corti-PS.

We reverse.

Background

The specification discloses that weight loss regimens involving limited food intake combined with exercise cause bodily stress. See page 1. In addition, in regimens designed to build strength and muscle mass, "the body may encounter extreme physical stress from systematic physical training trauma and

a substantially increased food intake." Id., pages 1-2. In both cases, the body responds to the stress by increasing production of cortisol. See page 3.

"Elevated cortisol is an indiscriminate metabolic/catabolic agent that breaks down the body's protein, including muscle tissue, into amino acids which are converted into glucose in the liver. Elevated cortisol is therefore counterproductive in both described situations of diet and exercise where high cost protein is metabolized into cheap sugar fuels. In dieting, desirable muscle is broken down along with stored fat, and in strenuous exercise, hard earned muscle is cannibalized leaving the body weak and exhausted." Id. "In the past, athletes and bodybuilders have relied on synthetic anabolic steroids for suppressing cortisol effects. . . . Anabolic steroids have well documented, dangerous side effects and are generally banned for athletes performing in most sanctioned athletic events." Id., pages 6-7.

Recent studies "have indicated that brain cortex-derived phosphatidylserine (BDPS) administered above threshold amounts suppressed elevation of cortisol levels during and after exercise." Id., page 7. "The soy-derived phosphatidylserine (SDPS) has clinically the same properties as the prohibitively expensive, brain-cortex derived phosphatidylserine (BDPS) in its anti-catabolic effect." Id. More specifically, "SDPS suppresses the elevation of cortisol resulting from stress. Where stress is self-induced as in physical training and dieting, ingestion of SDPS inhibits the detrimental process of protein catabolism, allowing retention of acquired muscle mass and synthesis of ingested protein." Id., pages 7-8.

Discussion

Claims 15 and 25 are the broadest product and method claims on appeal, respectively. Claim 15 is directed to a dietary supplement comprising "at least 100 mg of soy derived phosphatidylserine in combination with a physiologically beneficial amount of a protein supplement." Claim 25 is directed to a method of optimizing muscle development "during intense physical exercise," comprising ingesting soy derived phosphatidylserine "in an amount that suppresses elevation in the level of cortisol release during the physical exercise."

The examiner rejected all of the claims as obvious in view of the combined teachings of Fahey, Monteleone, Alekseyeva, Hager, Solgar, and Corti-PS. The examiner characterized Fahey as "teach[ing] physical fitness regimens for athletes. . . . In addition, Fahey et al. teach dietary regimens indicating that an adequate diet associated with heavy training includes optimal protein intake." Examiner's Answer, page 6. The examiner also relies on Fahey for its disclosure of the cortisol-blocking effect of anabolic steroids (id.) and the drawbacks of anabolic steroid use (id., pages 6-7).

The examiner concedes that Fahey "do[es] not teach administration of a phosphatidylserine supplement during physical training to optimize muscle development." Id., page 7. The examiner relies on Monteleone for its teaching of "administration of 50 or 75 mg of bovine cortex-derived phosphatidylserine to humans, followed by an induction of physical stress comprising physical exercise." Id. The examiner notes that Monteleone found that "administration of phosphatidylserine blunts the exercise-induced elevations in cortisol levels in the

blood." Id. Finally, the examiner relies on each of Alekseyeva, Hager, Solgar, and Corti-PS for their disclosures of soy-derived phosphatidylserine.

The examiner concluded that when the cited references are

> [t]aken together, it would have been obvious to one of ordinary skill in the art to provide a soy-derived phosphatidylserine supplement, in an appropriate amount, of the purpose of reducing stress-related inductions of cortisol, which, as a result, minimizes muscle breakdown, and for additionally providing a source of protein for enhancing muscle development during physical training regimens. As such, ingestion of a protein supplement in conjunction with a soy-derived phosphatidylserine supplement would intrinsically enhance the assimilation of the dietary protein supplement barring evidence to the contrary.

Id., page 9.

Appellant argues, inter alia, that the examiner's rejection is based on hindsight (Appeal Brief, pages 11 and 13), that the cited references do not suggest the claim limitations requiring ingesting protein along with soy-derived phosphatidylserine (see the Appeal Brief, page 14), and that Monteleone's disclosure of intravenously administered phosphatidylserine would not have suggested the claimed invention to a "serious sports nutrition specialist of good intent" (Appeal Brief, page 15).[1]

"In rejecting claims under 35 U.S.C. § 103, the examiner bears the initial burden of presenting a prima facie case of obviousness. Only if that burden is met, does the burden of coming forward with evidence or argument shift to the applicant." In re Rijckaert, 9 F.3d 1531, 1532, 28 USPQ2d 1955, 1956 (Fed. Cir.

[1] Appellant also argues that he has submitted evidence showing commercial success, recognition and adoption by others, and long-felt need in the art. See the Appeal Brief, page 12. Since we conclude that the references cited by the examiner do not support a prima facie case of

1993). The test of obviousness is "whether the teachings of the prior art, taken as a whole, would have made obvious the claimed invention." In re Gorman, 933 F.2d 982, 986, 18 USPQ2d 1885, 1888 (Fed. Cir. 1991).

"Most if not all inventions arise from a combination of old elements. Thus, every element of a claimed invention may often be found in the prior art. However, identification in the prior art of each individual part claimed is insufficient to defeat patentability of the whole claimed invention. Rather, to establish obviousness based on a combination of the elements disclosed in the prior art, there must be some motivation, suggestion or teaching of the desirability of making the specific combination that was made by the applicant." In re Kotzab, 217 F.3d 1365, 1369-70, 55 USPQ2d 1313, 1316 (Fed. Cir. 2000). An adequate showing of motivation to combine requires "evidence that 'a skilled artisan, confronted with the same problems as the inventor and with no knowledge of the claimed invention, would select the elements from the cited prior art references for combination in the manner claimed.'" Ecolochem, Inc. v. Southern Calif. Edison Co., 227 F.3d 1361, 1375, 56 USPQ2d 1065, 1075 (Fed. Cir. 2000).

In this case, we agree with Appellant that the prior art cited by the examiner could not have suggested the instantly claimed products and methods to a person of ordinary skill in the art. First, the examiner relies on Monteleone for its disclosure that phosphatidylserine blunted exercise-induced cortisol levels.

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obviousness, we need not address Appellant's declaratory evidence relating to secondary considerations.

See the Examiner's Answer, page 7. Thus, the examiner concludes, those of skill in the art would have found it obvious to replace the anabolic steroids discussed by Fahey with Monteleone's phosphatidylserine, in order to inhibit cortisol levels without getting the dangerous side-effects of anabolic steroids. See the Examiner's Answer, page 8.

We do not agree that the combined disclosures of Fahey and Monteleone would have made it obvious to administer phosphatidylserine as a replacement of anabolic steroids, with a reasonable expectation of success. Monteleone teaches intravenous administration of phosphatidylserine, while the instant claims are directed to dietary supplements or methods comprising "ingesting" phosphatidylserine. Thus, the examiner's position implicitly assumes that persons of skill in the art would have expected that the results seen by Monteleone's intravenous administration of phosphatidylserine would also have been expected for oral administration. The examiner, however, has cited no evidence to indicate that those of skill in the art considered oral and intravenous administration of phosphatidylserine to be equivalents.

In addition, the examiner has not adequately explained how the cited references would have made it obvious to combine phosphatidylserine with protein supplements, as required by, for example, claim 15. The examiner points to Fahey as disclosing the importance of "optimal protein intake" for athletes engaged in heavy training. Examiner's Answer, page 6. The pages of Fahey cited by the examiner, however, are at best equivocal on the importance of protein supplements. Fahey states that

- "[I]t must be emphasized that any increased protein requirement is restricted to athletes participating in intense programs. They do not apply to 'casual lifters' or 'weekend warriors.' It may be some time before nutrition experts agree on the optimal protein intake in elite athletes." Page 125.

- "It makes little sense for average healthy active adults consuming non-vegetarian diets to concern themselves with protein sources or protein supplements. As long as the minimum daily requirement for total protein is met and essential amino acids are provided, careful scrutiny of protein sources or paying money for expensive supplements is a waste of time. However, for the athlete involved in heavy weight training, consideration of the quantity, composition, and quality of proteins may be essential." Page 126.

- "[A]thletes who are considering protein supplements should probably use balanced peptide formulas rather than individual free form amino acids." Page 128.

- "[I]f essential amino acids are in short supply, the ability to use other amino acids for protein synthesis will be impaired. Again, the answer is to eat foods that contain the essential amino acids, and, if necessary, a supplement containing the correct balance of amino acids." Page 128.

Thus, Fahey teaches at best that protein supplements might be helpful for "elite athletes" who are "participating in intense programs" or "heavy weight training." On the other hand, Monteleone's conclusion regarding the cortisol-blunting effect of phosphatidylserine was based on data gathered from subjects who did not "participat[e] regularly in any kind of sport." Page 243. The examiner has not adequately explained what would have led the ordinarily skilled artisan, with no knowledge of the present disclosure, to combine teachings that were taught to be applicable to such different groups of people. See In re Dembiczak, 175 F.3d 994, 999, 50 USPQ2d 1614, 1617 (Fed. Cir. 1999) ("Measuring a claimed invention against the standard established by section 103

requires the oft-difficult but critical step of casting the mind back to the time of invention, to consider the thinking of one of ordinary skill in the art, guided only by the prior art references and the then-accepted wisdom in the field.").

Thus, we agree with Appellant that the references cited by the examiner would not have suggested combining the specific elements of the claimed products and methods, in the manner recited in the claims. The references therefore do not support a prima facie case of obviousness. The rejection under 35 U.S.C. § 103 is reversed.

Other Issues

As Appellant points out (Appeal Brief, pages 15-16), Monteleone 1992[2] appears to be closer prior art than the Monteleone reference applied by the examiner. Monteleone 1992 discloses administration of bovine cortex-derived phosphatidylserine to human subjects and measurement of the effect on, inter alia, cortisol levels after exercise. Monteleone 1992 concludes that "chronic oral administration of phosphatidylserine may counteract stress-induced activation of the hypothalamo-pituitary-adrenal axis in man." Abstract.

Claim 25 in the instant application is directed to a "method for optimizing muscle development during intense physical exercise which comprises ingesting an anti-catabolic nutrient, soy derived phosphatidylserine, in an amount that suppresses elevation in the level of cortisol release during the physical exercise." Monteleone 1992 appears to meet all the express limitations of this claim except

[2] Monteleone et al., "Blunting by chronic phosphatidylserine administration of the stress-induced activation of the hypothalamo-pituitary-adrenal axis in healthy men," Eur. J. Clin. Pharmacol., Vol. 42, pp. 385-388 (1992), of record.

that the reference's phosphatidylserine was cortex-derived rather than soy-derived.

It is unclear whether this difference distinguishes the claimed method from the method disclosed in the prior art. On the one hand, a preparation derived from bovine brains may well have a different composition than a preparation derived from soybeans, even if the main component of each preparation is phosphatidylserine. On the other hand, phosphatidylserine is phosphatidylserine, regardless of where it's from, and the instant specification indicates that "soy-derived phosphatidylserine (SDPS) has clinically the same properties as the prohibitively expensive, brain-cortex derived phosphatidylserine (BDPS) in its anti-catabolic effect." Page 7.

Upon return of this case, the examiner should consider whether the evidence of record is sufficient to conclude that the prior art process is the same as the process defined by claim 25. If so, the examiner could properly reject claim 25 (and possibly other claims as well) as anticipated, and shift the burden to Appellant to show a difference between the claimed process and the known one. See, e.g., In re Spada, 911 F.2d 705, 708, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990) ("[W]hen the PTO shows sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not.").

Summary

The references relied on by the examiner do not support a prima facie case of obviousness. The rejection under 35 U.S.C. § 103 is reversed.

REVERSED

Sherman D. Winters Administrative Patent Judge	))))) BOARD OF PATENT
Demetra J. Mills Administrative Patent Judge	)) APPEALS AND)) INTERFERENCES
Eric Grimes Administrative Patent Judge	))

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